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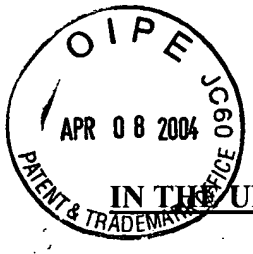

AF/3731

PATENT
Atty. Docket No. 2791 (203-2886)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:	Roby, et al.	EXAMINER:	G. Jackson
SERIAL NO.:	09/964,902	GROUP:	3731
FILED:	September 27, 2001	DATED:	April 6, 2004

FOR: **PRETREATMENT FOR LUBRICATED SURGICAL NEEDLES**

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPELLANTS' BRIEF

Sir:

Enclosed please find APPELLANTS' BRIEF in triplicate.

Also enclosed is a check in the amount of $330.00 to cover the appeal fee.

If the enclosed check is insufficient for any reason or becomes detached, please charge the required fee under 37 C.F.R. § 1.17 to Deposit Account No. 50-2140. Also, in the event any additional extensions of time are required, please treat this paper as a petition to extend the time as required and charge Deposit Account No. 50-2140. TWO (2) COPIES OF THIS SHEET ARE ENCLOSED.

Respectfully submitted,

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Dated: April 6, 2004

Jennifer J. Puente

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BRIEF ON APPEAL

Sir:

This is an appeal from a Final Office Action dated November 6, 2003 in the above-identified application. This Brief is accompanied by the requisite fees set forth in 37 C.F.R. §1.17(c).

I. REAL PARTY IN INTEREST

The real party in interest for this application is United States Surgical, a Division of Tyco Healthcare Group LP.

II. RELATED APPEALS AND INTERFERENCES

There are no other related appeals or interferences for this application.

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Dated: April 6, 2004

Jennifer J. Puente

III. STATUS OF CLAIMS

The instant application was originally filed with 27 claims. Claims 1-23 have been cancelled. Independent Claim 24 and dependent Claims 25-27 are pending in this application and are involved in this Appeal. Each of these claims stands finally rejected as set forth in the Office Action dated November 6, 2003 (the "Final Office Action") and as clarified in a supplemental Advisory Action dated March 22, 2004. An accurate copy of Claims 24-27 is provided in the Appendix.

IV. STATUS OF AMENDMENTS

The Advisory Action dated February 20, 2004 indicates that the Amendment after Final Rejection filed on January 12, 2004 would be entered for purposes of this Appeal.

V. SUMMARY OF THE INVENTION

Claim 24 is directed to a surgical needle having reduced penetration force. The surgical needle possesses an acid-treated surface and a silicone-containing coating on at least a portion of the acid-treated surface. (Specification page 4, lines 4-6; page 8, line 10). The penetration force of the surgical needle on a fifth pass through a microporous polyurethane member of about 0.042 inches thickness is at least 10% less than that of the same surgical needle possessing the same silicone-containing coating, but lacking an acid-treated surface. (Specification page 4, lines 9-13; page 14, line 17 to page 18, line 3.)

VI. ISSUES

The following issue is on appeal:

whether the reduced penetration force needle of Claim 24 is anticipated by the blackened needle disclosed in U.S. Patent No. 4,959,068 to Bendel et al.

VII. GROUPING OF CLAIMS

The patentability of Claims 25-27 stands or falls together with the patentability of independent Claim 24.

VIII. ARGUMENT

In finally rejecting Claim 24 as anticipated by U.S. Patent No. 4,959,068 to Bendel et al. ("Bendel et al."), the Examiner has utterly failed to establish where, in fact, Bendel et al. discloses the needle of Claim 24 and improperly ignored the limitations of Claim 24.

Claim 24 recites a surgical needle having reduced penetration force including, inter alia, a surgical needle having an acid-treated surface and a silicone-containing coating on at least a portion of the acid treated surface, "wherein the surgical needle has a penetration force on a fifth pass through microporous polyurethane member of about 0.042 inches thickness that is at least 10% less than the penetration force on a fifth pass through a microporous polyurethane member of about 0.042 inches thickness of a needle having the same silicone-containing coating on the same surgical needle having no surface that is acid treated." Nowhere does Bendel et al. disclose such a needle.

A. <u>The Examiner has improperly ignored the limitations of Claim 24</u>

Claims are typically drafted in the form of a preamble, transition, and one or more elements . Pursuant to the "all elements" or "all limitations" rule of claim interpretation, each element constitutes a limitation or narrowing of the scope of the claim. *See, e.g., Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.,* 149 F.3d 1309, 1317, 47 USPQ2d 1272, 1277 n.A1 (Fed. Cir. 1998). The subject matter of a "wherein" clause includes such claim limitations. *See Griffin v. Bertina*, 285 F.3d 1029, 62 USPQ2d 1431 (Fed. Cir. 2002). *Griffin v. Bertina* was an interference proceeding where the count concerned a method for diagnosing thrombosis. The junior party's evidence did not demonstrate the recognition of a correlation between a point mutation in a sequence of a blood factor (Factor V) and an increased risk of thrombosis, as required by the count's preamble and "wherein" clauses. While the junior party tried to argue that the content of the "wherein" clauses was not necessary for interpreting the scope of the count, the Federal Circuit affirmed the Board of Patent Appeals & Interferences' interpretation which gave a limiting effect to the "wherein" clauses. Specifically, the Federal Circuit noted the "wherein" clauses were necessary and limited the claim by referring "to the point mutation, giving meaning and purpose to the manipulative steps." *Id.*

Here, the Examiner has wholly ignored the limitations found in the "wherein" clause of Claim 24, arguing in the Final Office Action that "the function recited in the whereby clause is capable of being performed by Bendel et al. since there's no structure difference between the claim and the reference." However, this argument ignores the fact that the limitations of Claim 24 in the "wherein" clause, i.e., the surgical needle that has been acid treated has a

penetration force that is at least 10% less than the penetration force of a needle having the same silicone-containing coating that has not been acid treated, limits the needle of Claim 24 by giving meaning and purpose to the reduced penetration force of such a needle. This is precisely the type of claim limitation the Court found properly included in interpreting the count in *Griffin v. Bertina* and thus cannot be ignored in Claim 24.

B. Bendel et al. fails to describe the improved penetration forces of Claim 24

Bendel et al. is merely concerned with improving visibility of its needles. Bendel et al.'s needles are acid treated to blacken the needle to form a dark, non-reflective, non-flaking surface having improved visibility in the surgical field: Bendel et al. is not concerned with improving penetration forces by pre-treating a needle. Bendel et al. requires a strong acid (sulfuric is the only acid mentioned), the presence of a dichromate (which one skilled in the art reading Bendel et al. has no basis to expect any improvement in penetration force) and temperature in excess of 100 °C. (Bendel et al. states that this is important to obtain the blackening of the needle at column 3, lines 30-32). Only this combination of conditions is described to provide Bendel et al.'s specific blackening effect.

Bendel et al. does not appreciate that maintaining good penetration force after multiple passes through tissue is a concern. While the examples of Bendel et al. report penetration characteristics, there is no appreciation that an acid pre-treatment provides any improvement in penetration force after five passes through a material. Based on the specific and severe reaction conditions required to achieve the blackening, there is no reasonable basis for one skilled in

the art to derive any relevant teaching or suggestion from Bendel et al. regarding an improvement in penetration force.

While the Examiner was invited in the Response to the Final Office action to identify where, in fact, Bendel et al. provides any suggestion that Bendel et al.'s process improves penetration force ***compared to a needle that has not undergone acid treatment***, the Examiner failed to do so. The Examiner merely noted that Bendel et al. suggests the needles can be lubricated, and that "Applicants' statement that Bendel et al. does not address improving penetration force is not correct since it is clearly discussed in column [sic], line 58." (See first paragraph of Examiner's Comment attached to the February 20, 2004 Advisory Action.)

However, while Bendel et al. tested penetration characteristics of its needles, nowhere is there a discussion of an improvement in penetration forces as a result of acid treatment. In fact, and to the contrary, Bendel et al. states his desired goal was not to improve penetration characteristics of needles, but to obtain penetration characteristics for blackened needles that were similar to unblackened needles:

> "In accordance with the present invention, my new sterile surgical needle has a uniformly dark and non-reflective surface. The surface is non-flaking and the ***needle has penetration characteristics substantially the same as needles having shiny and polished surfaces***. "
>
> (Bendel et al. at column 1, lines 55-59. Emphasis added.)

In addition, nowhere in Bendel et al. is there any comparison of a blackened needle with an untreated needle, nor is there any appreciation that the Bendel et al. needles would have improved penetration characteristics compared with needles that were not acid treated. Thus, Bendel et al. fails to disclose or

suggest the needle of Claim 24.

C. **The acid utilized by Bendel et al. does not improve the penetration forces of its needles**

While the Examiner asserted in the Final Office Action that Bendel et al.'s needles are capable of performing the function of Claim 24's wherein clause, i.e., the surgical needle that has been acid treated has a penetration force that is at least 10% less than the penetration force of a needle having the same silicone-containing coating that has not been acid treated, where a reference is silent on an asserted inherent characteristic, to serve as an anticipation any extrinsic evidence used to fill such a gap in the reference must be clear that missing descriptive matter is necessarily present in the thing described and that it would be recognized by those of ordinary skill in the art. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ 2d 1746, 1749, (Fed. Cir. 1991).

Here, the Examiner's position that Bendel et al.'s acid treatment will produce needles with reduced penetration characteristics is contrary to the express teachings of Bendel et al.: Bendel et al. describe the electrical activation of the needle surface, not the acid treatment, as necessary to avoid dulling and roughening of the needle surface, and thereby avoid increasing the penetration forces of the needle.

Figure 3 of Bendel et al. provides a graphical depiction of its process. Referring to Figure 3, Bendel et al. describes the treatment of its needles as follows:

> "The selected needle is treated (Box B) to render the surface of the needle activated; that is, to allow the chromium on the surface of the needle to form oxides. Two techniques for activating the surface of the needle are to either electroclean or electropolish the needle immediately

before the blackening treatment. If the surface of the needle is not suitably activated, a thin layer of the metal is removed in the process and the cutting edges dulled and the surface roughened or channeled. The dulling and roughening greatly increases the penetration forces required with the needle and make the needle unsuitable for use in many surgical procedures where tissue trauma must be kept to a minimum."

(Bendel et al. at column 3, lines 6-18.)

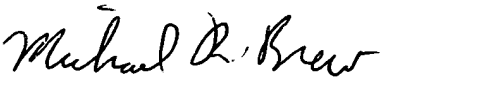
As is clear from Bendel et al.'s description of the process, Step B, the activation step, prevents the dulling and roughening of the needle which will otherwise occur in Bendel et al.'s process, which includes the acid treatment step (Figure 3, step C). This dulling and roughening, if allowed to occur, increases the penetration forces of Bendel et al.'s needle. The activation step of Bendel et al. is conducted by electrical processes, i.e., electroclean or electropolish, not treatment with an acid, and is conducted ***before*** Bendel et al.'s needles are submersed in a solution of sulfuric acid, potassium dichromate and water (Cf. Bendel et al. Figure 3, steps B and C).

Thus, contrary to the Examiner's assertions, one skilled in the art would look to the activation step of Bendel et al., i.e., electrochemical processes, to prevent an increase in penetration forces of Bendel et al.'s needles that would otherwise occur as a result of the acid treatment of Bendel et al. Accordingly, Bendel et al. fails to anticipate the needles of Claim 24.

IX. CONCLUSION

In view of the foregoing analysis and remarks, Appellants submit that Claim 24 is not anticipated by Bendel et al. Claims 25-27, which depend from Claim 24, incorporate all the limitations of Claim 24 therein. Thus, all of the claims pending in this application, namely Claims 24-27, are in condition for allowance.

Respectfully submitted,



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X. APPENDIX OF CLAIMS

24. A surgical needle having reduced penetration force comprising:

a surgical needle having an acid-treated surface; and

a silicone-containing coating on at least a portion of the acid treated surface,

wherein the surgical needle has a penetration force on a fifth pass through microporous polyurethane member of about 0.042 inches thickness that is at least 10% less than the penetration force on a fifth pass through a microporous polyurethane member of about 0.042 inches thickness of a needle having the same silicone-containing coating on the same surgical needle having no surface that is acid treated.

25. A surgical needle as in claim 24 wherein the silicone-containing coating comprises an aminoalkyl siloxane.

26. An article of manufacture as in claim 24 wherein the silicone-containing coating comprises an interpenetrating network.

27. An article of manufacture as in claim 24 wherein the silicone-containing coating comprises a copolymer of an aminoalkyl siloxane and a second siliconization material.